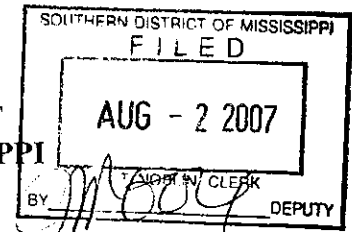


IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI



Estate of Bobbie G. Overton, Sr.  
by Personal Representative of the Estate,  
Bobbie H. Overton; Estate of James Ellis;  
Carolyn Evans; Ruby Giles;  
Richard Griffith; Elaine Joyce Lee;  
Estate of Cornelius Lewis; Jackie Lewis

PLAINTIFFS

VS.

CAUSE NO.: 3:07cv450HTW LRA

Pfizer Inc., Monsanto Company, G. D. Searle LLC,  
Pharmacia Corporation

DEFENDANTS

---

COMPLAINT

---

TRIAL BY JURY IS REQUESTED

INTRODUCTION

1. This is a civil action brought by the above Plaintiffs, for injuries resulting in heart attacks, strokes and/or blood clots. Plaintiffs were prescribed and used the prescription medication CELEBREX (Celecoxib). This action seeks monetary damages for personal injuries caused by the drugs named herein and ingested by Plaintiffs.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. § 1332 because the parties are citizens of different states and the amount in controversy exceeds \$75,000.00.

3. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiffs' claims occurred, in part, in the Southern District of Mississippi.

#### PARTIES

a. Plaintiff, Estate of James Ellis, was an adult resident citizen of Claiborne, County, Mississippi.

b. Plaintiff, Carolyn Evans, is an adult resident citizen of Rankin, County, Mississippi.

c. Plaintiff, Ruby Giles, is an adult resident citizen of Hinds, County, Mississippi.

d. Plaintiff, Richard Griffith, is an adult resident citizen of Madison, County, Mississippi.

e. Plaintiff, Elaine Joyce Lee, is an adult resident citizen of Rankin, County, Mississippi.

f. Plaintiff, Estate of Cornelius Lewis, was an adult resident citizen of Hinds, County, Mississippi.

g. Plaintiff, Jackie Lewis, is an adult resident citizen of Hinds, County, Mississippi.

h. Plaintiff, Estate of Bobbie G. Overton, was an adult resident citizen of Copiah, County, Mississippi.

5. Defendant G. D. Searle LLC. (hereinafter "Searle") is a subsidiary of Pharmacia Corporation, and is upon information, knowledge and belief an Illinois Corporation. As such, Defendant Searle can be served through its principal address: CT Corporation System, 208 South LaSalle Street, Suite 814 Chicago, Illinois 60604. At all times relevant hereto, Searle as a subsidiary of Pharmacia Corporation and Pharmacia Corporation (hereinafter "Pharmacia"); at all times relevant to this action was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib).

6. Defendant Pharmacia Corporation is a Delaware Corporation licensed and registered to do business in Mississippi and can be served through its registered agent: CT Corporation System, 645 Lakeland East Drive Flowood, Mississippi 39232.

7. Defendant Monsanto Company (hereinafter "Monsanto") is the parent of Pharmacia and is a Delaware Corporation. At all times relevant hereto Monsanto through its subsidiary companies was in the business of manufacturing, marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Defendant Monsanto is licensed and registered to do business in Mississippi, and may be served through its agent: Corporation Service Company, 506 South President Street Jackson, Mississippi 39201.

8. Defendant Pfizer Inc. (hereinafter "Pfizer") is a Delaware corporation, and at all times relevant hereto Pfizer was in the business of marketing, selling and distributing the pharmaceutical product Celebrex (Celecoxib). Defendant Pfizer is licensed and registered to do business in Illinois and may be served through its registered agent: CT Corporation System, 645 Lakeland East Drive Flowood, Mississippi 39232.

#### **JOINDER ALLEGATIONS**

9. Plaintiffs' claims are typical of each other's claim, Plaintiffs purchased Celebrex for musculoskeletal joint pain associated with osteoarthritis, among other maladies.

10. There are questions of law and fact common to the Plaintiffs which include, but are not limited to:

a. Whether Defendants exercised reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib).

b. Whether Defendants breached that duty and were negligent in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib) in that: Celebrex (Celecoxib) was defective when put on the market by Defendants; that with such defect, Celebrex (Celecoxib) was reasonably certain to be dangerous when put to normal use; and that Defendants failed to use reasonable care in designing or making Celebrex (Celecoxib) or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

i. Failing to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, to the potential risks and serious side effects of the drug;

ii. Failing to adequately and properly test and inspect the drug before placing the drug on the market;

iii. Failing to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, heart attack, stroke, life threatening allergic and/or skin reactions and/or death.

iv. Failing to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and other serious side effects associated with the drug, including, among other things, heart attack, stroke, life threatening allergic and/or skin reactions and/or death;

v. Failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;

vi. Failing to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug;

vii. Encouraging misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiffs, in order to make a profit from sales;

viii. Whether Defendants knew or should have known that Celebrex (Celecoxib) caused unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiffs, were not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied Celebrex (Celecoxib) knowing that there were safer methods for pain relief.

11. These common issues of law and fact predominate over individual issues pertaining to individual Plaintiffs and permissive joinder is a superior method of resolving those claims.

#### BACKGROUND

12. Celebrex is a pharmaceutical treatment for musculoskeletal joint pain associated with osteoarthritis, among other maladies. The Removing Defendants Searle, Pharmacia, Monsanto and Pfizer did manufacture, design, package, market and distribute this drug. The Sales Representatives Defendants encouraged the use of this drug in improper customers, misrepresented the safety and effectiveness of this drug and concealed or understated its dangerous side effects. These Defendants aggressively marketed this drug directly to the consuming public, although only available through prescription, through the use of various

---

marketing mediums, including, but not limited to, print and television advertisements. These Defendants did this to increase sales and profits.

13. At all times relevant hereto, the Defendants actually knew of the defective nature of their product as herein set forth, yet continued to design, manufacture, market, distribute and sell their product so as to maximize sales and profits at the expense of the general public's health and safety in conscious disregard of the foreseeable harm caused by this product. Defendants' conduct exhibits such an entire want of care as to establish that their actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiffs' individual rights, and hence punitive damages are appropriate.

14. This Complaint seeks redress for damages sustained by Plaintiffs use of Celebrex (Celecoxib), manufactured and sold by Pharmacia, G.D. Searle, Monsanto and Pfizer, the Defendants herein.

15. The Plaintiff, Estate of James Ellis was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Estate of James Ellis had no history of heart or stroke problems. Subsequent to the Plaintiff Estate of James Ellis' ingestion of Celebrex he suffered a heart attack and stroke. The Plaintiff, Carolyn Evans was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Carolyn Evans had no history of heart or stroke problems. Subsequent to the Plaintiff Carolyn Evans' ingestion of Celebrex she suffered a heart attack. The Plaintiff, Ruby Giles was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Ruby Giles had no history of heart or stroke problems. Subsequent to the Plaintiff Ruby Giles' ingestion of Celebrex she suffered a heart related injury. The Plaintiff, Richard Griffith was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Richard Griffith had no history of heart or stroke problems. Subsequent to the Plaintiff Richard Griffith's ingestion of Celebrex he

suffered a heart related injury. The Plaintiff, Elaine Joyce Lee was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Elaine Joyce Lee had no history of heart of stroke problems. Subsequent to the Plaintiff Elaine Joyce Lee's ingestion of Celebrex she suffered a heart attack. The Plaintiff, Estate of Cornelius Lewis was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Estate of Cornelius Lewis had no history of heart of stroke problems. Subsequent to the Plaintiff Estate of Cornelius Lewis' ingestion of Celebrex he suffered a stroke. The Plaintiff, Jackie Lewis was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Jackie Lewis had no history of heart of stroke problems. Subsequent to the Plaintiff Jackie Lewis' ingestion of Celebrex she suffered a heart related injury. The Plaintiff, Estate of Bobbie G. Overton was prescribed Celebrex. Prior to the ingestion of Celebrex the Plaintiff Estate of Bobbie G. Overton had no history of heart of stroke problems. Subsequent to the Plaintiff Estate of Bobbie G. Overton's ingestion of Celebrex she suffered a heart attack.

16. The damages sought herein are the direct and proximate result of Defendants' wrongful conduct in connection with designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the prescription drug Celebrex (Celecoxib).

17. At all times relevant hereto, Defendants were engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the pharmaceutical drug Celebrex (Celecoxib) throughout the United States.

18. Had Defendant properly disclosed the risks associated with using Celebrex (Celecoxib), the Plaintiffs would not have taken it for treatment of pain associated with injury.

19. This action is being brought in the Circuit Court of Tunica County, because the amount of recovery sought exceeds the jurisdictional levels of all lower courts.

**A. Facts Regarding CELEBREX: Science And Other Cox-2 Inhibitors**

20. CELEBREX is among a class of pain medications called non-steroidal anti-inflammatory drugs ("NSAIDs"). Aspirin, naproxen (trade name Aleve®), and ibuprofen (trade name Advil®) are examples of well-known NSAIDs.

21. NSAIDs reduce pain and inflammation by blocking the body's production of pain transmission enzymes called cyclooxygenase, COX-1 and COX-2. COX enzymes trigger the sequential oxidation of various fatty acids to create prostaglandins. Prostaglandins are important cogs in the physiology of pain, igniting hormone-like actions in the immediate vicinity of the cells that release them, thereby inducing inflammation, pain, and fever.

22. Because COX enzymes and prostaglandins increase the pain associated with tissue injury, the synthesis of prostaglandins by cells of injured tissue becomes a reasonable target for pain-management drugs.

23. Traditional NSAIDs like aspirin, ibuprofen and naproxen inhibit both COX-1 and COX-2 enzymes simultaneously, providing relief from inflammation and pain, but at the cost of potential adverse gastrointestinal effects, as the prostaglandins that are supported by COX-1 enzymes are involved in the production of gastric mucus which protects the stomach wall from the hydrochloric acid present in the stomach. By blocking the COX-1 enzyme, the body's ability to protect gastric tissue is hampered and, as a result, can cause harmful gastrointestinal side effects, including stomach ulceration and bleeding.

24. Defendants and other pharmaceutical companies set out to remedy these gastrointestinal side effects suffered by some NSAID users by developing "selective" inhibitors,



called coxibs, which targeted only COX-2 production, thus (allegedly) allowing for proper maintenance of gastric tissue while still reducing inflammation. Their development was based on the hypothesis that COX-2 was the source of prostaglandins E2 and I2, which mediate inflammation, and that COX-1 was the source of the same prostaglandins in the stomach lining. By not inhibiting COX-1, whose products provide cytoprotection in the gastric epithelium, these coxibs were thought to decrease the incidence of gastric side effects when compared to traditional NSAIDS that inhibit both COX-1 and COX-2.

25. In making this decision, however, Defendants and their predecessors in interest either intentionally ignored and/or recklessly disregarded current medical knowledge that selective COX-2 inhibition lowers prostaglandin I2 levels, the predominant COX-2 product responsible for preventing platelet aggregation and clotting, while leaving thromboxane A2, the potent COX-1 platelet aggregator and vasoconstrictor, unaffected. By selectively inhibiting prostaglandin I2 without similarly suppressing its COX-1 counterpart, CELEBREX and other coxibs expose their users to a host of clot-related cardiovascular risks, including heart attack, stroke, and unstable angina.

26. On June 29, 1998, SEARLE and PFIZER filed for FDA approval of Celecoxib, its first major COX-2 inhibitor drug, under the trade name CELEBREX. The FDA granted preliminary approval of the new drug on December 31, 1998 for the relief of signs and symptoms of adult osteoarthritis and rheumatoid arthritis. A year later, on December 23, 1999, the FDA granted accelerated approval of CELEBREX for a second indication; the reduction of intestinal polyps as an adjunct to endoscopy and surgery in patients with familial adenomatous polyposis (FAP), a rare genetic disorder.

27. In late January 1999, following FDA approval, PFIZER publicly launched CELEBREX, their new "blockbuster" drug, in one of the largest direct-to-consumer marketing campaigns ever undertaken for prescription drugs. PFIZER's massive marketing campaign fraudulently and misleadingly depicted CELEBREX as a much safer and more effective pain reliever than less inexpensive traditional NSAIDs. Defendants and their representatives and agents misrepresented the safety profile of CELEBREX to consumers, the medical community, healthcare providers, and third party payors.

**B. Facts Regarding Celebrex's Safety And Defendants' Knowledge Thereof**

28. The potential for cardiovascular risk of selective COX-2 inhibitors was known to Defendants long before the FDA granted market approval in December 1998. By 1997, and prior to the submission of the New Drug Application (the "NDA") for CELEBREX, Defendants were aware that, by selectively inhibiting only the COX-2 enzyme, CELEBREX altered the homeostatic balance between prostacyclin synthesis and thromboxane and thereby increased the prothrombotic effects of the drugs, causing blood clots to form in those who ingested it. *See* Topol, E.J., *et al.*, "Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors," JAMA, August 22, 2001 at 954.

29. Pharmacologist Dr. Garrett Fitzgerald of the University of Pennsylvania reported in an editorial published in *The New England Journal of Medicine* on October 21, 2004, that contemporaneous with Defendants' launch it was known that selective COX-2 inhibitors, such as CELEBREX, suppressed the formation of prostaglandin 1-2 in healthy volunteers, inhibited platelet aggregation in vitro, and may predispose patients to myocardial infarction or thrombotic stroke. Fitzgerald, G.A., Patrono C., "The Coxibs, Selective Inhibitors of Cyclooxygenase-2," *N Engl J Med* 2001;345:433-442.

30. Early FDA updates in March and April of 1999 similarly acknowledged this known risk, but noted, based upon PFIZER's representations, that CELEBREX "does not affect platelet aggregation (clumping), an important part of the blood clotting process." *See* FDA Updates, "New Arthritis Drug May Have Fewer Side Effects," FDA Consumer March-April 1999.

31. Based on the studies performed on CELEBREX, other COX-2 inhibitors, and basic research on this type of selective inhibitor which had been widely conducted, Defendants knew when CELEBREX was being developed and tested that selective COX-2 inhibitors posed serious cardiovascular risks for anyone who took them, and presented a specific additional threat to anyone with existing heart disease or cardiovascular risk factors.

32. Despite years of studies on selective COX-2 inhibitors, as well as the disturbing new studies specifically analyzing the risks of CELEBREX, Defendants failed to take any action to protect the health and welfare of patients, opting instead to continue promoting the drug for sale even after the FDA's Drug Safety and Risk Management Advisory Committee and Arthritis Drug Advisory Committee meetings.

### **C. CELEBREX and Cox-2 Studies Did Not Show CELEBREX to be Safe**

#### **1. CELEBREX Long-Term Arthritis Safety Study (CLASS)**

33. In September 1998, PHARMACIA sponsored an allegedly independent CELEBREX Long-Term Arthritis Safety Study ("CLASS"). The multicenter, double-blind, parallel group study sought to compare the incidence of clinically significant upper gastrointestinal events between CELEBREX 400 mg BID and Ibuprofen 800 mg. (CLASS data is found in NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. CLASS

was submitted to the FDA on June 12, 2000 and reviewed by James Witter, M.D., Ph.D. (FDA Medical Officer) on September 20, 2000.)

34. On September 13, 2000, Defendants released the results of the CLASS study in the *Journal of American Medicine*. Silverstein, F.E., et al., "Gastrointestinal Toxicity with Celecoxib vs Nonsteroidal Anti-inflammatory Drugs for Osteoarthritis and Rheumatoid Arthritis: The CLASS Study: A Randomized Controlled Trial," 284 JAMA 1247 (2000). Researchers enthusiastically reported a "lower incidence of symptomatic ulcers and ulcer complications combined, as well as other clinically supported toxic effects, compared with NSAIDs at standard doses."

35. Although Defendants touted the CLASS study as the primary evidence to support its theory that CELEBREX was safer for consumers who could not tolerate traditional NSAIDs in their gastrointestinal system, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the results, risks and defects of the CLASS study. Among other things, Defendants failed to release the study's complete twelve month results releasing only the first six months of trials, reported biased and misleading results, limited conclusions to upper gastrointestinal events despite other known risks factors, and understated known cardiovascular risks.

36. Despite Defendants' favorable CLASS Study conclusions, no other reviewing or administrative body was able to substantiate those findings. The FDA Medical Officer Review of the CLASS data found CELEBREX to be no more efficacious than other traditional NSAIDS comparators. *See generally*, FDA Medical Officer Review, NDA 20-998/S-009 submitted to the FDA by SEARLE on June 12, 2000. According to the FDA's review of the CLASS data: "Celecoxib did not demonstrate any statistical superiority to NSAIDs (pooled) or either

comparator (diclofenac and ibuprofen) with regards to the primary safety endpoint of CSUGIE (Clinically Significant Upper Gastrointestinal Adverse Events) at any point in the trial although there were trends that favored celecoxib." (FDA CLASS Review).

37. The FDA Arthritis Advisory Committee similarly found no "clinically meaningful" safety advantage of CELEBREX over older NSAIDs (FDA CDER Arthritis Advisory Committee, February 7th and 8th, 2001, Gaithersburg, Maryland). The CLASS Study failed to demonstrate a superior safety record over ibuprofen or pooled NSAID data. Based on this information, the Committee advised that further studies be done to assess the risk of COX-2 drugs and NSAIDS when taken with aspirin.

38. In a June 2002 editorial, the *British Medical Journal* chastised the Study's "misleading" and "seriously biased" nature; noting that the complete results "clearly contradict[ed] the published conclusions," and warning against the dangers of "overoptimistic," "short-term" data and "post hoc changes to the protocol." Juni, Peter, *et. al.*, "Are Selective COX 2 Inhibitors Superior To Traditional Non Steroidal Anti-Inflammatory Drugs?" *BMJ* 2002; 324:1287-1288. Most noticeably, the CLASS study considered only six months of data despite the fact that researchers at that point had 12 months of data that, when analyzed as a whole, showed no significant difference. Instead of releasing the complete 12-month results from CLASS, PFIZER relied on and published only the first six months of data. *JAMA* 2000, 283:1455-1460. The results of the completed study revealed the real truth: CELEBREX offered no gastrointestinal (GI) benefit. Almost all ulcer-related complications that had occurred during the second half of the CLASS trials were in users of CELEBEX. These results clearly contradict the published CLASS conclusions.

39. Editors of the Journal of the American Medical Association (JAMA) and other medical experts were reportedly, "flabbergasted" when they realized they had been "duped" by only being provided with the first six months of CLASS data. Okie S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:II. The *Washington Post* reported JAMA editors noting: "When all of the data were considered, most of CELEBREX's apparent [GI] safety advantage disappeared."

40. Institutional bias also appeared to play a role in the Study's biased conclusions.

41. According to the *Washington Post*, all sixteen CLASS authors were either employees of PHARMACIA or paid consultants of the company. Okie, S., *"Missing data on Celebrex: Full study altered picture of drug,"* Washington Post 2001 Aug 5;Sect A:II. Moreover, at least one author, Dr. M. Michael Wolfe, a gastroenterologist from Boston University, admits he was duped by PHARMACIA. In the summer of 2000, *The Journal of the American Medical Association* asked Wolfe to participate in the "six-month" trial. Wolfe found the study, tracking 8,000 patients over a six-month period, persuasive, and penned a favorable review, which helped to drive up CELEBREX sales. It was not until early the next year, while serving on the FDA's Arthritis Advisory Committee, that Wolfe learned the study had run for one year, not six months, as the company had originally led both Wolfe and the *Journal* to believe. *Id* Here again, when the complete data was considered, most of CELEBREX advantages disappeared.

42. Defendants also limited conclusions of the CLASS study to upper gastrointestinal events, despite other known risks factors, and understated known cardiovascular risks. A metastudy by the Cleveland Clinic published in the Journal of the American Medical Association analyzed data from two major studies, including CLASS, funded by the drug companies and two smaller ones-all for cardiovascular risks. Debabrata Mukherjee, *et al.*, *"Risk of Cardiovascular*

*Events Associated with Selective Cox-2 Inhibitors*," 286 JAMA 954 (2001).) The metastudy found that PHARMACIA failed to identify and study cardiovascular risks for their products. The annualized heart attack rates for patients taking Vioxx or Celebrex, the researchers found, were "significantly higher" than those in a group taking placebos. "The available data raise a cautionary flag about the risk of cardiovascular events with Cox-2 inhibitors," they concluded.

43. "A total of 36 deaths occurred during the [CLASS] study or during post study follow-up: 19 in the celecoxib group, 9 in the diclofenac group and 8 in the ibuprofen group .... Most deaths were cardiovascular in nature." FDA CLASS Review at 54. The increased number of adverse cardiovascular events in the CELEBREX group was not surprising, as they were also revealed in the original New Drug Application (NDA) submitted for CELEBREX. "In the original NDA, myocardial infarction was noted to occur at a higher rate in celecoxib-treated as compared to placebo treated patients. In the long term trial (Trial 024) that was included in the NDA submission, the predominate (>90%) cause of death for patients taking celecoxib at any dose was cardiovascular." FDA CLASS Review at 78.

44. Public Citizen, a public watchdog organization, also reviewed the CLASS data in its entirety. A complete review reveals the combined anginal adverse events were 1.4% in the CELEBREX group versus 1.0% in either NSAID group. Specifically, the rate of heart attack in the CELEBREX was double that of the other two NSAIDs, 0.2% vs. 0.1%, respectively.

45. Eric Topol of the Cleveland Clinic reached a similar conclusion, noting that the CLASS trial MI rate was 1.6% in CELEBREX group (at a dosage of 400 mg twice a day) and 1.2% in the ibuprofen group for the 1739 patients taking low-dose aspirin. Topol noted that this numerical excess, albeit not statistically significant, was also found in the 6229 patients not taking aspirin in the trial. Eric 1. Topol, *"Arthritis Medicines and Cardiovascular Events House*



of Coxibs," JAMA 293:366. Based on this data, Topol and his colleagues concluded: "It is mandatory to conduct a trial specifically assessing cardiovascular morbidity." *Id.* Unfortunately, no such trials were ever initiated, delaying the official warnings of CELEBREX and jeopardizing countless lives in the process.

46. The CLASS data proves that PFIZER knew that its first generation COX-2 inhibitor, CELEBREX, caused a disproportionately and statistically significant high number of adverse cardiovascular events before it was introduced to the market in January 1999. According to Public Citizen, after CLASS, the FDA recommended a trial to specifically assess the cardiovascular risks of COX-2 inhibitors. The Adenoma Prevention with Celecoxib (APC) trial was intended to be this placebo-controlled trial of CELEBREX.

## **2. APC Trial**

47. In early 2000, the National Cancer Institute (NCI), in collaboration with SEARLE and PFIZER, initiated the Adenoma Prevention with Celecoxib (APC) trial, a randomized, double-blind, placebo-controlled study to discover the efficacy of CELEBREX in preventing the growth of pre-cancerous colon polyps. N.ENG.J. MED.352;11 at 1072. The trial involved 2026 patients across the country with randomization to one of three groups: (1) placebo; (2) 200 mg CELEBREX twice daily; and (3) 400 mg CELEBREX twice daily. The patients, each of whom had an adenomatous polyp removed before enrollment, were followed up for a mean of 33 months while taking the study drug, with the primary objective of limiting the development of colorectal cancer.

48. On December 17, 2004, the National Cancer Institute suspended the use of CELEBREX for all participants in the APC trial due to "significant excess of cardiovascular death, myocardial infarction (MI) and stroke." Eric J. Topol, *"Arthritis Medicines and*



*Cardiovascular Events - House of Coxibs*, "JAMA 293:366. Analysis by an independent Data Safety Monitoring Board (DSMB) showed a two to three fold increased risk of major fatal and non-fatal cardiovascular events for participants taking the drug compared to those on a placebo with a secondary dose-response effect.

49. The absolute excess of major cardiovascular events of 13/1000 patients at the 800 mg dose (400 mg 2x day) was strikingly similar to the results of trials with rofecoxib and valdecoxib, both selective NSAID COX-2 inhibitors removed for the market for their significant cardiovascular risks. Eric J. Topol, *"Arthritis Medicines and Cardiovascular Events - House of Coxibs*, "JAMA 293:366.

50. The FDA reported similar results, noting:

In the National Cancer Institute's Adenoma Prevention with Celecoxib (APC) trial in patients at risk for recurrent colon polyps, a 2-3 fold increased risk of serious adverse CV events was seen for CELEBREX compared to placebo after a mean duration of treatment of 33 months. There appeared to be a dose response relationship, with a hazard ratio of 2.5 for CELEBREX 200 mg twice daily and 3.4 CELEBREX 400 mg twice daily for the composite endpoint of death from CV causes, myocardial infarction (MI), or stroke.

April 7, 2005 FDA Alert: [www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm](http://www.fda.gov/cder/drug/infopage/celebrex/celebrex-hcp.htm).

51. The dosage noted in the study is itself important for two reasons: first, there appears to be an association between dosage and the increase in adverse cardiovascular events; second, most patients increase dosage. PFIZER knew patients were increasing their dosages as noted in the CLASS Study: "Interestingly ... up to 70% of patients increased their dose for celecoxib." FDA CLASS Review at 74. Thus, PFIZER was aware of "dosage creep."

### **3. Other CELEBREX Trials**

52. Several other CELEBREX trials also gave Defendants insight into the cardiovascular risks presented by CELEBREX. The Prevention of Spontaneous Adenomatous Polyps (Pre SAP) trial identified the death rate from cardiovascular causes (heart attack, stroke,

heart failure, angina, or need for CV procedure) as 3.6% with CELEBREX as compared to 2.7% for placebo.

53. Public Citizen also reviewed the results of Study IQ IQ5-97-02-001 which reflected "the combined rate of all serious cardiovascular adverse events in patients getting a placebo was 2.1% but was greatly increased in those getting celecoxib to 7.7%, a 3.6 fold increase in CV risk in those people taking celecoxib. ( $p=0.03$ )."*Public Citizen*, January 26, 2005, Dr. Sidney M. Wolfe. According to Dr. Sidney Wolfe, "The study revealed a significantly increased rate (3.6-fold) of serious CV adverse events and more than a doubling in the rate of CV deaths in people using celecoxib compared to those using placebo." *Id.*

#### **4. Cox-2 Studies: VIGOR and APPROVe**

54. PFIZER also had access to other data which indicated a cardiovascular risk with its drugs. Specifically, PFIZER had knowledge of two studies conducted by Merck related to its Cox-2 inhibitor Vioxx - Vioxx Gastrointestinal Outcomes Research (VIGOR) and Adenomatous Polyp Prevention (APPROVe).

##### **a. VIGOR**

55. In 2000, The FDA Medical Officer Review of CLASS specifically noted the VIGOR trial and the concern over serious adverse cardiovascular events. FDA CLASS Review at 78.

56. According to VIGOR (near acronym for Vioxx Gastrointestinal Outcomes Research) Vioxx patients experienced 20% more serious clinical adverse events (statistically significant); they experienced 4.6 times more hypertension events serious enough to warrant discontinuation, 1.7 times more edema events, and 1.85 times as many congestive heart failure

adverse events. By two measures of cardiovascular events related to blood clots, Vioxx had twice the risk of naproxen and the results were considered statistically significant.

57. The VIGOR study comprised the most definitive scientific evidence ever obtained about pharmaceutical products. It was a large, randomized clinical trial, the gold standard of medical research. It was a safety study with endpoints set in advance. As Merck stated many times, it was designed to provide definite proof of safety, convincing enough to silence the most skeptical critics. In medical terms, the VIGOR results raised the question of whether selective inhibition of COX-2 was a monumental mistake from the start. While the NSAID risks to the GI system were real and sometimes fatal, they were dwarfed by the cardiovascular risks of the arthritis population that needed these drugs on a daily basis. All makers of NSAIDs, including Defendants, were aware of these results.

**b. APPROVe**

58. Anxious to put safety questions surrounding Vioxx to rest, Merck designed another large scale trial, Adenomatous Polyp Prevention (APPROVe), which was intended to test the drug's ability to prevent or shrink colon polyps, but would also compare the cardiovascular safety of Vioxx to a placebo control. According to the analysis conducted by Public Citizen of the APPROVe data: Vioxx "doubled the risk of any thrombotic cardiovascular event" and "doubled the risk of MI (myocardial infarction a/k/a heart attack)"<sup>1</sup>. *Public Citizen*, January 24, 2005, at 15. Despite the available CELEBREX data and other information related to Vioxx, PFIZER never paused to reevaluate the CELEBREX data and studies.

<sup>1</sup> Although Merck claims that the two-fold risk of heart attacks and strokes seen in the APPROVe trial did not emerge until after patients had been taking the drug for 18 months, closer analysis indicates that significant increase in risk of heart attack was evident in as little as 4 months time.

59. The scientific data available during and after CELEBREX's approval process made clear to Defendants that their formulation of CELEBREX would cause a higher risk of blood clots, stroke and/or myocardial infarctions among CELEBREX consumers, alerting them to the need to do additional and adequate safety studies.

60. As stated by Dr. Topol on October 21, 2004, in *The New England Journal of Medicine*, outlining Defendants' failure to have conducted the necessary trials before marketing to humans "it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of (COX-2 inhibitors). Such a trial needed to be conducted in patients with established coronary artery disease, who frequently have coexisting osteoarthritis requiring medication and have the highest risk of further cardiovascular events."

61. Dr. Topol was also the author on the study published in August 2001 in JAMA (listed above) that reported an increased risk of thrombotic cardiovascular events in persons who used COX-2 inhibitors.

62. Based upon readily available scientific data, Defendants knew, or should have known, that their pre-approval testing of CELEBREX did not adequately represent the cross-section of individuals who were intended consumers and therefore, likely to take CELEBREX. Therefore, Defendants' testing and studies were grossly inadequate.

63. Had Defendants done adequate testing prior to approval and market launch, rather than the extremely short duration studies done on the small size patient base that was actually done, the Defendants' scientific data would have revealed significant increases in incidence of strokes and myocardial infarctions among the intended and targeted population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed

---

product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

64. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

65. Defendants' failure to conduct adequate testing and/or additional testing prior to market launch was based upon their desire to generate maximum financial gains for themselves and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

66. At the time Defendants manufactured, advertised, and distributed CELEBREX to consumers, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAIDs.

#### **D. Facts Regarding Defendants' Marketing And Sale Of CELEBREX**

67. Such an ineffective and unreasonably dangerous drug could only be widely prescribed as a result of a tremendous marketing campaign. In addition to being aggressive, the Defendants' marketing campaign was fraudulent and misleading. But for fraudulent and misleading advertising, consumers, including the Plaintiffs, would not have purchased CELEBREX, a more costly prescriptive drug, ineffective for its intended purposes.

68. Defendant's marketing was so fraudulent that the FDA issued three Warning Letters to Defendants in October 1999, April 2000, and November 2000, all finding that

Defendants were unlawfully making false or misleading statements concerning the safety and/or efficacy of CELEBREX. The November letter cited two direct-to-consumer television advertisements that overstated the efficacy of CELEBREX. The FDA ordered that SEARLE immediately cease distribution of the misleading ads.

69. On February 2001, the FDA issued a Warning Letter to PHARMACIA stating that promotional activities from marketing CELEBREX were unlawful because they were "false, lacking in fair balance, or otherwise misleading." The FDA found that CELEBREX had been promoted for unapproved uses, in unapproved dosing regimens, and that the marketers had made unsupportable claims that CELEBREX was safer and more effective than other NSAIDs.

70. In August 2001, it was revealed that PHARMACIA had misrepresented the results of a post-marketing clinical study of CELEBREX when submitting it for publication. PHARMACIA selectively omitted portions of the data relating to adverse effects. The *Washington Post* reported on August 5, 2001 that, "the study had lasted a year, not six months as ... thought. Almost all of the ulcer complications that occurred during the second half of the study were in CELEBREX users. When all of the data were considered, most of CELEBREX's apparent safety advantage [as compared to traditional NSAIDs] disappeared."

71. On January 10, 2005 the FDA again issued PFIZER a written reprimand for its promotional activities. The reprimand reads: "These five promotional pieces [3 CELEBREX and 2 Bextra] variously: omit material facts ... and make misleading safety, unsubstantiated superiority, and unsubstantiated effectiveness claims." Amid continued frustration with PFIZER's continually misleading marketing strategy and ever surmounting evidence of cardiovascular dangers, the FDA Advisory Panel voted overwhelmingly that the company should never again advertise the drug [CELEBREX]."

72. At all times relevant herein, Defendants engaged in a marketing campaign with the intent that consumers would perceive CELEBREX as a safer and better drug than its other NSAIDs and, therefore, purchase CELEBREX.

73. Defendants widely and successfully marketed CELEBREX throughout the United States by, among other things, conducting promotional campaigns that misrepresented the efficacy of CELEBREX in order to induce a widespread use and consumption. CELEBREX was represented to aid the pain and discomfort of arthritis, osteoarthritis, and related problems. Defendants made misrepresentations by means of media advertisements, and statements contained in sales literature provided to Plaintiffs' prescribing physicians.

74. Despite knowledge of the dangers presented by CELEBREX, Defendants and Defendants' predecessors in interest, through their officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of CELEBREX and failed to warn the public, including Plaintiffs, of the serious risk of injury occasioned by the defects inherent in CELEBREX. Defendants and their officers, agents and managers intentionally proceeded with the inadequate safety testing, and then the manufacturing, sale and marketing of CELEBREX, knowing that persons would be exposed to serious potential danger, in order to advance their own pecuniary interests. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Plaintiffs.

75. In an elaborate and sophisticated manner, Defendants aggressively marketed CELEBREX directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on third party payors, medical care organizations, and large institutional buyers (e.g., hospitals) to include CELEBREX on their formularies. Faced

with the increased demand for the drug by consumers and health care professionals that resulted from Defendants' successful advertising and marketing blitz, third party payors were compelled to add CELEBREX to their formularies. Defendants' marketing campaign specifically targeted third party payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of CELEBREX.

76. Defendants represented that CELEBREX was similar to ibuprofen and naproxen but was superior because it lacked any of the common gastrointestinal adverse side effects associated with these and other non-steroidal anti-inflammatory drugs ("NSAIDS"). Defendants promoted CELEBREX as a safe and effective alternative that would not have the same deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

77. Yet, CELEBREX possessed dangerous and concealed or undisclosed side effects, including the increased risk of serious cardiovascular events, such as heart attacks, unstable angina, cardiac clotting, deep vein thrombosis, hypertension, and cerebrovascular events, such as strokes. In addition, CELEBREX, which is significantly more expensive than traditional NSAIDs<sup>2</sup>, was actually was no more effective than traditional and less expensive NSAIDs and, just like traditional NSAIDs, carried a risk of perforations, ulcers, and gastrointestinal bleeding. Yet, Defendants chose not to warn about these risks and dangers.

78. Defendants knew of these risks before the U.S. Food and Drug Administration (the "FDA") approved CELEBREX for sale, but Defendants ignored, downplayed, suppressed, omitted, and concealed these serious safety risks and denied inefficacy in its promotion, advertising, marketing, and sale of CELEBREX. Defendants' omission, suppression, and

<sup>2</sup> The cost of Celebrex is at least \$3-\$6 per day, while an over-the-counter NSAID can cost \$.50 or less per day.



concealment of this important information enabled CELEBREX to be sold to, and purchased, or paid for by, the Consumers at a grossly inflated price.

79. Consequently, CELEBREX captured a large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone, sales of CELEBREX exceeded \$2 billion, despite the significantly higher cost of CELEBREX as compared to other pain relievers in the same family of drugs.

80. Because Defendants engaged in a promotional and marketing campaign that featured an advertising blitz directly targeted to consumers, that touted CELEBREX as a safer drug than other drugs in its class, while uniformly failing to disclose the health risks of CELEBREX, Defendants were able to justify pricing CELEBREX significantly higher than the cost of generic aspirin. In reality, that price inflation was not justified. Had Defendants disclosed the truth about CELEBREX, Defendants would not and could not have reaped the billions of dollars in CELEBREX sales that were achieved as a direct result of the concealment, omission, suppression, and obfuscation of the truth.

81. The Defendants intentionally, deliberately, knowingly, and actively concealed, omitted, suppressed, and obfuscated important and material information regarding the risks, dangers, defects, and disadvantages of CELEBREX from Plaintiffs, the public, the medical community, and the regulators. This concealment and omission was deliberate, knowing, active, and uniform, was intended to induce and maximize sales and purchases of CELEBREX, and prevented Plaintiffs from obtaining all the material information that would be important to them decision as a reasonable person to purchase, pay for, and/or use CELEBREX.

---

82. Defendants' systematic, active, knowing, deliberate, and uniform concealment, omissions, suppression, and conduct caused Plaintiffs to purchase, pay for, and/or use CELEBREX; and caused Plaintiffs' losses and damages as asserted herein.

83. Had Defendants done adequate testing prior to approval and "market launch," the defendants' scientific data would have revealed significant increases in stroke and myocardial infarction amongst the intended population of CELEBREX consumers. Adequate testing would have shown that CELEBREX possessed serious side effects. Defendants should have taken appropriate measures to ensure that their defectively designed product would not be placed in the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the scope and severity of symptoms of those side effects should have been made.

84. In fact, post-market approval data did reveal increased risks of clotting, stroke and myocardial infarction, but Defendants intentionally suppressed this information in order for them to gain significant profits from continued CELEBREX sales.

85. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch," and active concealment and failure to warn the medical community and general public of the known cardiovascular risks of CELEBREX was particularly negligent, reckless and/or malicious given the drug's known target market. Defendants were well aware that most patients taking CELEBREX are elderly and have higher risk of developing cardiovascular risks to begin with. Nearly half of the patients with arthritis have coexisting cardiovascular disease, and most patients, as discovered in the CLASS study, were prone to higher dosing.

86. Defendants' failure to conduct adequate testing and/or additional testing prior to "market launch" was based upon their desire to generate maximum financial gains for themselves

and to gain a significant market share in the lucrative multi-billion dollar COX-2 inhibitor market.

87. At the time Defendants manufactured, advertising, and distributed CELEBREX to consumers including Plaintiffs, Defendants intentionally or recklessly ignored and/or withheld information regarding the increased risks of hypertension, stroke and/or myocardial infarctions because Defendants knew that if such increased risks were disclosed, consumers would not purchase CELEBREX, but instead would purchase other cheaper and safer NSAID drugs.

### FIRST CAUSE OF ACTION

#### NEGLIGENCE

88. Plaintiffs repeat and reallege each of the allegations contained in this Complaint.

89. Defendants, directly or indirectly, negligently and/or defectively designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Celebrex (Celecoxib).

90. At all times material hereto, Defendants had a duty to users and/or consumers of Celebrex (Celecoxib), including Plaintiffs to exercise reasonable care in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib).

91. Defendants breached that duty and were negligent in the design, testing, inspection, manufacture, assembly, development, labeling, sterilization, licensing, marketing, advertising, promotion, sale, packaging, supply and/or distribution of Celebrex (Celecoxib) in that: Celebrex (Celecoxib) was defective when put on the market by Defendants; that with such defect, Celebrex (Celecoxib) was reasonably certain to be dangerous when put to normal use;

and that Defendants failed to use reasonable care in designing or making Celebrex (Celecoxib) or in inspecting it for defects. Specifically, Defendants breached their duty by, among other things:

- a. Failing to include adequate warnings that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, to the potential risks and serious side effects of the drug;
- b. Failing to adequately and properly test and inspect the drug before placing the drug on the market;
- c. Failing to conduct sufficient testing and inspection of the drug which, if properly performed, would have shown that the drug had serious side effects, including, but not limited to, heart attack, stroke, life threatening allergic and/or skin reactions and/or death.
- d. Failing to adequately warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and other serious side effects associated with the drug, including, among other things, heart attack, stroke, life threatening allergic and/or skin reactions and/or death;
- e. Failing to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the significant risks associated with the use of the drug;
- f. Failing to recall and/or remove the drug from the stream of commerce despite the fact that Defendants knew or should have known of the defective and unreasonably dangerous nature of the drug, including the significant health risks associated with the use of the drug;

g. Encouraging misuse and overuse while failing to disclose the side effects of the drug to the medical, pharmaceutical and/or scientific communities, and users and/or consumers, including Plaintiffs, in order to make a profit from sales.

92. Defendants knew or should have known that Celebrex (Celecoxib) caused unreasonably dangerous risks and serious side effects of which users and/or consumers of the drug, including Plaintiffs, were not aware. Defendants nevertheless advertised, promoted, marketed, sold, distributed and/or supplied Celebrex (Celecoxib) knowing that there were safer methods for pain relief.

93. As a direct, legal, proximate and producing result of the negligence of Defendants, Plaintiffs sustained substantial injuries including, among other things, a heart attack. This injury caused extensive pain and suffering and severe emotional distress and substantially reduced Plaintiffs' ability to enjoy life. In addition, Defendants' negligence caused Plaintiffs to expend substantial sums of money for medical, hospital, and related care.

94. As a direct, legal, proximate and producing result of the negligence of Defendants, Plaintiffs was injured in health, strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to physical injury and damages.

95. As a direct, legal, proximate and producing result of the negligence of Defendants, Plaintiffs required reasonable and necessary health care treatment and services and had incurred expenses therefore. Defendants' negligence was a contributing cause of Plaintiffs' injuries and Plaintiffs' economic and non economic loss. As a result of Defendant's negligence, Plaintiffs has suffered and will continue to suffer.

96. By reason of the foregoing, Plaintiffs was damaged by the negligence and wanton and willful recklessness of the Defendants. The amount sought herein exceeds the jurisdictional limits of all lower courts that would otherwise have jurisdiction over this matter.

## SECOND CAUSE OF ACTION

### STRICT PRODUCTS LIABILITY DEFECTIVE DESIGN

97. Plaintiffs repeat and reallege each of the allegations contained in this Complaint.

98. At an times material hereto, Defendants have engaged in the business of designing, testing, inspecting, manufacturing, assembling, developing, labeling, sterilizing, licensing, marketing, advertising, promoting, selling, packaging, supplying and/or distributing the drug Celebrex (Celecoxib), which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiffs.

99. At all times material hereto, Celebrex (Celecoxib) was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendants in a defective and unreasonably dangerous condition in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, the drug contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the drug, including Plaintiffs, to risks which exceeded the benefits of the drug;

b. The drug was insufficiently tested;

c. The drug caused harmful side effects that outweighed any potential utility;

d. The drug was not accompanied by adequate labeling or instructions for use to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and serious side effects associated with its use;

e. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Celebrex (Celecoxib) should not have been marketed in that condition.

100. At all times the drug Celebrex (Celecoxib) was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed, it was expected to reach, and did reach, users and/or consumers of the drug across the United States, including Plaintiffs, without substantial change in the defective and unreasonably dangerous condition in which it was sold.

101. At all times, Plaintiffs used Celebrex (Celecoxib) for its intended or reasonably foreseeable purpose.

102. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Celebrex (Celecoxib), Plaintiffs sustained substantial injuries including, among other things, heart attack. These injuries caused extensive pain and suffering and severe emotional distress and substantially reduced Plaintiffs's ability to enjoy life. In addition, the defective and unreasonably dangerous condition of Celebrex (Celecoxib) caused Plaintiffs to expend substantial sums of money for medical, hospital, and related care.

103. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Celebrex (Celecoxib), Plaintiffs were injured in health,

Celebrex II  
Cause No.:

strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to physical injury and damages.

104. As a direct, legal, proximate and producing result of the defective and unreasonably dangerous condition of Celebrex (Celecoxib), Plaintiffs required reasonable and necessary health care treatment and service and had incurred expenses therefore.

105. By reason of the foregoing, Plaintiffs was damaged by the wanton and willful recklessness of the Defendants, who will be liable to Plaintiffs. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

### THIRD CAUSE OF ACTION

#### STRICT PRODUCTS LIABILITY FAILURE TO WARN

106. Plaintiffs repeat and reallege each of the allegations contained in this Complaint.

107. Celebrex (Celecoxib) was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, to the dangerous risks and reactions associated with Celebrex (Celecoxib) when used for its intended or reasonably foreseeable purpose. Those dangerous risks and reactions included, but were not limited to, heart attack, stroke, life threatening allergic and/or skin reactions and/or death and other serious and life threatening side effects.

108. At all times, Plaintiffs used the drug for its intended or reasonably foreseeable purpose.

---



109. Plaintiffs could not have discovered any defect in the drug through the exercise of care.

110. Defendants, as manufacturers of a prescription drug, are held to the level of knowledge of an expert in the field.

111. The warnings that were given by Defendants were not accurate or clear and/or were ambiguous.

112. Defendants had a continuing duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and serious side effects associated with the use of Celebrex (Celecoxib).

113. As a direct, legal, proximate and producing result of Defendant's failure to warn, Plaintiffs sustained harm, including, among other things, heart attack. These injuries caused extensive pain and suffering and severe emotional distress and substantially reduced Plaintiffs' ability to enjoy life. In addition, Defendants' failure to warn caused Plaintiffs to expend substantial sums of money for medical, hospital, and related care.

114. As a direct, legal, proximate and producing result of Defendants' failure to warn, Plaintiffs was injured in health, strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to the physical injuries and damages.

115. As a direct, legal, proximate and producing result of Defendants' failure to warn, Plaintiffs required reasonable and necessary health care treatment and services and had incurred expenses therefore.

116. By reason of the foregoing, Plaintiffs was damaged by the wanton and willful recklessness of the Defendants who will be liable to Plaintiffs. The amount sought herein

exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

#### FOURTH CAUSE OF ACTION

##### BREACH OF EXPRESS WARRANTY OF MERCHANTABILITY

117. Plaintiffs reallege all prior paragraphs of this complaint as if fully set out herein.

118. The Removing Defendants and Sales Representatives Defendants made express representations to the consuming public at large through their aggressive marketing and advertising campaigns relative to their product, Celebrex.

119. The Removing Defendants through their detail sales representatives, including Sales Representatives Defendants, made representations of the safety and efficacy of their product, Celebrex.

120. Celebrex does not conform to the express representations made through the Defendants' advertising and marketing efforts.

121. Celebrex does not conform to the express representations made by Sales Representatives Defendants.

122. Defendants' conduct in this matter was a contributing cause of injuries and damages suffered by Plaintiffs.

123. Wherefore, this Plaintiffs demand judgment against Defendants in such an amount of compensatory and punitive damages as a jury deems reasonable, plus cost.

#### FIFTH CAUSE OF ACTION

##### BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

124. Plaintiffs repeat and reallege each of the allegations contained in the Complaint.

125. 130. Defendant is a "merchant" as defined in *Mississippi Code Annotated*

*Uniform Commercial Code* § 75-2-104.

126. Celebrex (Celecoxib) is a "good" as defined *Code Annotated Uniform Commercial Code* § 75-2-105.

127. At the time that Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed the drug Celebrex (Celecoxib), Defendants knew of the intended, reasonably foreseeable and/or ordinary use of Celebrex (Celecoxib) and impliedly warranted the drug to be of merchantable quality and safe and fit for such use.

128. Plaintiffs, in ingesting Celebrex (Celecoxib), reasonably relied upon the skill and judgment of Defendants as to whether Celebrex (Celecoxib) was of merchantable quality and safe and fit for its intended, reasonably foreseeable and/or ordinary use.

129. In breach of the implied warranty given by Defendants, Celebrex (Celecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because the product was and is un-merchantable, in a defective condition and unreasonably dangerous and unfit for the intended, reasonably foreseeable and/or ordinary purpose for which it was intended as described above.

130. In breach of the implied warranty given by Defendants, Celebrex (Celecoxib) was not of merchantable quality or safe or fit for its intended, reasonably foreseeable and/or ordinary use because, among other things:

a. Use of Celebrex (Celecoxib) carried a risk of, among other things, heart attack, stroke and/or death and other serious and life threatening side effects;

b. Defendants failed to include adequate warnings with the drug that would alert the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, of the potential risks and serious side effects of the drug;

c. Defendants failed to provide adequate post-marketing warnings or instructions after Defendants knew or should have known of the potential risks and serious side effects associated with the use of the drug.

131. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiffs sustained substantial injuries including, among other things, heart attack. These injuries caused extensive pain and suffering and severe emotional distress and substantially reduced Plaintiffs' ability to enjoy life. In addition, Defendants' failure to warn caused Plaintiffs to expend substantial sums of money for medical, hospital and related care.

132. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiffs has been injured in health, strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to the physical injuries and damages.

133. As a direct, legal, proximate and producing result of Defendants' breach of warranty, Plaintiffs required reasonable and necessary health care treatment and services and had incurred expenses therefore.

134. As a result of Defendant's breach of warranty, Plaintiffs has suffered and will continue to suffer.

135. By reason of the foregoing, Plaintiffs has been damaged by the wanton and willful recklessness of the Defendants who will be liable to Plaintiffs. The amount sought herein exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

#### SIXTH CAUSE OF ACTION

#### FRAUD

136. Plaintiffs repeat and reallege each of the allegations contained in the Complaint.

---

137. Defendants recklessly, knowingly, intentionally, and fraudulently misrepresented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, the safety and efficacy of the drug and/or recklessly, knowingly, intentionally and fraudulently concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, material, adverse information regarding the safety and efficacy of Celebrex (Celecoxib).

138. Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, with the intent that they reach users and/or consumers of the drug, including Plaintiffs.

139. Defendants either knew or should have known that the representations were false.

140. Defendants made the misrepresentations and/or actively concealed information concerning the safety and efficacy of the drug with the intention and specific desire that the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, would rely on such in selecting Celebrex (Celecoxib) as a pain reliever.

141. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Celebrex (Celecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

142. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs. Specifically, Defendants misrepresented to and/or actively concealed from

the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, that:

- a. There had been insufficient studies regarding the safety and efficacy of the drug;
- b. The drug was fully and adequately tested, despite knowing that there had been insufficient or inadequate testing of the drug;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious prothrombotic and allergic and/or skin reactions, including, but not limited to, adverse cardiovascular events and/or Stevens-Johnson Syndrome/toxic epidermal necrolysis;
- d. Defendants knew or should have known of reports of increased heart attacks, allergic and/or skin reactions and/or strokes associated with the use of the drug;
- e. Defendants knew or should have known of the greatly increased risk of developing heart attacks, allergic and/or skin reactions and/or strokes associated with use of Celebrex (Celecoxib); yet, despite this they were downplaying the risk of the drug.

143. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by Defendants, its sales representatives, employees, distributors, agents and/or detail persons.

144. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and serious side effects associated with the use of Celebrex (Celecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs,

about the potential risks and serious side effects associated with the use of Celebrex (Celecoxib) in a timely manner, yet they failed to provide such warning.

145. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Celebrex (Celecoxib) to her detriment.

146. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs sustained substantial injuries including, among other things, heart attack. These injuries caused extensive pain and suffering and severe emotional distress for Plaintiffs, and substantially reduced Plaintiffs' ability to enjoy life. In addition, the misrepresentations of Defendants caused Plaintiffs to expend substantial sums of money for medical, hospital, and related care.

147. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs have been injured in health, strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to the physical injury and damages.

148. As a result of Defendants' fraud, Plaintiffs have suffered and will continue to suffer.

149. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs required reasonable and necessary health care treatment and service and had incurred expenses therefore.

150. By reason of the foregoing, Plaintiffs have been damaged by the wanton and willful recklessness of the Defendants who will be liable to Plaintiffs. The amount sought herein

---

exceeds the jurisdictional limits of all lower courts which would otherwise have jurisdiction over this matter.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

151. Plaintiffs repeat and reallege each of the allegations contained in the Complaint.

152. Defendants negligently misrepresented or failed to exercise reasonable care in representing to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, the safety and efficacy of the drug and/or negligently concealed or failed to exercise reasonable care by concealing and failing to disclose to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, material, adverse information regarding the safety and efficacy of Celebrex (Celecoxib).

153. Defendants' misrepresentations were communicated to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, with the intent that they reach users and/or consumers of the drug, including Plaintiffs.

154. Defendants made these misrepresentations and/or actively concealed information concerning the safety and efficacy of Celebrex (Celecoxib) in its labeling, advertising, product inserts, promotional materials or other marketing efforts.

155. Defendants either knew or should have known that the representations were false.

156. Defendants knew or should have known that the misrepresentations and/or omissions concerning the safety and efficacy of the drug would be relied upon by the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, in selecting Celebrex (Celecoxib) as a pain reliever.

---



Celebrex II  
Cause No.:

157. Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew or should have known that its drug product had defects, dangers and characteristics that were other than what Defendants had represented to the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs. Specifically, Defendants misrepresented to and/or actively concealed from the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, that:

- a. There had been insufficient studies regarding the safety and efficacy of the drug;
- b. The drug was fully and adequately tested, despite the fact that there had been insufficient or inadequate testing of the drug;
- c. Prior studies, research, reports and/or testing had been conducted linking the use of the drug to serious adverse cardiovascular events, allergic and/or skin reactions and strokes;
- d. Defendants knew or should have known of reports of heart attacks associated with the use of the drug;
- e. Defendants knew or should have known of the greatly increased risk of heart attacks, strokes, life threatening allergic and/or skin reactions and/or death and other serious and life threatening side effects associated with the drug; yet, despite this was downplaying the risks of the drug.

158. The misrepresentations of and/or active concealment by Defendants were perpetuated directly and/or indirectly by the Removing Defendants, their sales representatives,

Celebrex II  
Cause No.:

employees, distributors, agents and/or detail persons, including the Sales Representatives Defendants.

159. The misrepresentations of and/or active concealment by Defendants constitute a continuing tort. Indeed, through Defendants' product inserts, Defendants continued to misrepresent the potential risks and complications associated with Celebrex (Celecoxib). Moreover, Defendants had a post-sale duty to warn the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the drug, including Plaintiffs, about the potential risks and serious side effects associated with the use of Celebrex (Celecoxib) in a timely manner, yet it failed to provide such warning.

160. Plaintiffs justifiably relied on and/or were induced by the misrepresentations and/or active concealment of Defendants to purchase and ingest Celebrex (Celecoxib) to his detriment.

161. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs sustained harm, including, among other things, heart attack. These injuries have caused extensive pain and suffering and severe emotional distress and substantially reduced Plaintiffs's ability to enjoy life. In addition, the misrepresentations of Defendants caused Plaintiffs to expend substantial sums of money for medical, hospital, and related care.

162. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs were injured in health, strength and activity and suffered physical injuries as well as mental anguish. All of said injuries caused Plaintiffs intense anxiety, distress, fear, pain, suffering and distress secondary to the physical injury and damages.

---

163. As a direct, legal, proximate and producing result of the misrepresentations of Defendants, Plaintiffs required reasonable and necessary health care treatment and service and had incurred expenses therefore.

164. As a result of the misrepresentations of the Defendants, Plaintiffs have suffered and will continue to suffer.

165. By reason of the foregoing, Plaintiffs have been damaged by the wanton and willful recklessness of these Defendants who will be liable to Plaintiffs. The amount sought herein exceeds the jurisdictional limits of all lower courts, which would otherwise have jurisdiction over this matter.

**WHEREFORE, PREMISES CONSIDERED,** Plaintiffs request that the Defendants be cited to appear and answer herein; that upon final trial herein, Plaintiffs recover damages as set forth above from Defendants, including cost of Court, pre-judgment and post-judgment interest at the legal rates, and that Plaintiffs have such other and further relief, both general and special, at law and in equity, to which she may be justly entitled under the facts and attending circumstances.

Respectfully Submitted,

*Levi Boone, III*

BY: \_\_\_\_\_

Atty. Levi Boone, III

**OF COUNSEL:**

**BOONE LAW FIRM, P.A.**  
401 WEST SUNFLOWER ROAD  
P. O. BOX 1772  
CLEVELAND, MS 38732-1772  
TEL: (662) 843-7946  
FAX: (662) 843-7950  
EMAIL: [LBOONE@BOONELAWFIRM.COM](mailto:LBOONE@BOONELAWFIRM.COM)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

## I. (a) PLAINTIFFS

THE ESTATE OF BOBBIE G. OVERTON, SR. BY THE PERSONAL REPRESENTATIVE OF THE ESTATE BOBBIE H. OVERTON; ET AL

(b) County of Residence of First Listed Plaintiff Copiah

(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

BOONE LAW FIRM, P. A. P. O. BOX 1772 CLEVELAND, MS 38732

662-843-7946

## DEFENDANTS

PFIZER, INC., ET AL

County of Residence of First Listed Defendant

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

SOUTHERN DISTRICT OF MISSISSIPPI

FILED

AUG - 2 2007

## II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

## III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State ☒ 1 PTF ☐ 1 DEF Incorporated or Principal Place of Business In This State ☐ 4 ☐ 4
- Citizen of Another State ☐ 2 ☒ 2 Incorporated and Principal Place of Business In Another State ☐ 5 ☐ 5
- Citizen or Subject of a Foreign Country ☐ 3 ☐ 3 Foreign Nation ☐ 6 ☐ 6

## IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability <b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property					

## V. ORIGIN

(Place an "X" in One Box Only)

- ☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

## VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

28 USC 1332

Brief description of cause:

PHARMACEUTICAL LIABILITY

## VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

## DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

## VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

08/01/2007

SIGNATURE OF ATTORNEY OF RECORD

*John Boone III*

FOR OFFICE USE ONLY

RECEIPT # 5030542 AMOUNT \$1350.00

APPLYING IFP

JUDGE

MAG. JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI**

**ESTATE of BOBBIE G. OVERTON, SR., by  
Personal Representative of the Estate, BOBBIE  
H. OVERTON, ESTATE of JAMES ELLIS,  
CAROLYN EVANS, RUBY GILES, RICHARD  
GRIFFITH, ELAINE JOYCE LEE, ESTATE  
OF CORNELIA LEWIS, JACKIE LEWIS,**

**PLAINTIFFS**

**vs.**

**CIVIL ACTION NO. 3:07-cv-450-TSL-JCS**

**Pending Transfer to MDL-1699  
(In re Bextra and Celebrex Marketing,  
Sales Practices and Products  
Liability Litigation)**

**PFIZER INC., MONSANTO COMPANY, G.D.  
SEARLE LLC, and PHARMACIA  
CORPORATION,**

**DEFENDANTS**

**DEFENDANTS' CORPORATE DISCLOSURE STATEMENT**

Pursuant to Federal Rule of Civil Procedure 7.1 and to enable judges and magistrate judges of the Court to evaluate possible disqualification or recusal, the undersigned attorneys for Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC ("Searle") submit this their Corporate Disclosure Statement and state:

1. Pfizer is a publicly traded company which does not have any parent corporations or any publicly traded shareholders with ten percent (10%) or more of its shares.
2. Pharmacia is a wholly-owned subsidiary of Pfizer.
3. Searle is a wholly-owed third-tier subsidiary of Pharmacia.

Dated this 17<sup>th</sup> day of December, 2007.

Respectfully submitted,

By: /s/ Walter T. Johnson

Walter T. Johnson (MBN 8712)  
Joseph J. Stroble (MBN 10779)  
WATKINS & EAGER, P.L.L.C.  
400 East Capitol Street, Suite 300  
Jackson, Mississippi 39205-0650  
Telephone: (601) 948-6470  
Facsimile (601) 354-3623

OF COUNSEL:

SOCHA, PERCZAK, SETTER & ANDERSON, P.C.

Charles Q. Socha (MBN 101382)

K. Michelle Anderson (MBN 101421)

Denver Financial Center Tower 1

1775 Sherman Street, Suite 1925

Denver, Colorado 80203

Telephone: (303) 832-7265

Facsimile: (303) 832-7438

ATTORNEYS FOR PFIZER INC., PHARMACIA  
CORPORATION, AND G.D. SEARLE LLC

**CERTIFICATE OF SERVICE**

I hereby certify that on December 17, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF system and forwarded on December 17, 2007, via United States first-class mail, postage prepaid, a true and correct copy to the following:

Levi Boone, III  
BOONE LAW FIRM, P.A.  
401 West Sunflower Road  
P.O. Box 1722  
Cleveland, Mississippi 38732-1772

/s/ Walter T. Johnson  
Walter T. Johnson

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Pharmacia Corporation  
Attention: Legal Department  
C.T. Corporation System  
645 Lakeland East Drive  
Jackson, MS 39232

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

DATE

11-20-07



A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Pfizer, Inc.  
Attention: Legal Department  
235 East 42<sup>nd</sup> Street Frnt.  
New York, New York 10017-5703

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

DATE

11-20-07

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Monsanto, Inc.  
Attention: Legal Department  
Corporation Service Company  
506 South President Street  
Jackson, MS 39201

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

DATE

11-20-07

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: G.D. Searle LLC  
Attention: Legal Department  
CT Corporation System  
208 South LaSalle Street, Suite 814  
Chicago, Illinois 60604

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

DATE

11-20-07

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Pharmacia Corporation  
Attention: Legal Department  
C.T. Corporation System  
645 Lakeland East Drive  
Jackson, MS 39232

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

DATE

11-20-07

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Pfizer, Inc.  
Attention: Legal Department  
235 East 42<sup>nd</sup> Street Frnt.  
New York, New York 10017-5703

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

DATE

(By) DEPUTY CLERK

11-20-07

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: Monsanto, Inc.  
Attention: Legal Department  
Corporation Service Company  
506 South President Street  
Jackson, MS 39201

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

CLERK

(By) DEPUTY CLERK

11-20-07  
DATE

A0 440 (Rev. 8/01) in a Civil Action

UNITED STATES DISTRICT COURT  
Southern District of Mississippi,

SUMMONS IN A CIVIL CASE

ESTATE OF BOBBIE G. OVERTON, SR., ET AL  
PLAINTIFFS

VS.

CASE NUMBER: 3:07-CV-00450 TSL-JCS

PFIZER, INC., ET AL

DEFENDANTS

TO: G.D. Searle LLC  
Attention: Legal Department  
CT Corporation System  
208 South LaSalle Street, Suite 814  
Chicago, Illinois 60604

YOU ARE HEREBY SUMMONED and required to serve on PLAINTIFF'S ATTORNEY (name and address)

Levi Boone, III, Esq.  
Boone Law Firm, P.A.  
401 W. Sunflower Road  
P.O. Box 1772  
Cleveland, MS 38732

an answer to the complaint which is served on you with this summons, within 30 days after service of this summons on you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. Any answer that you serve on the parties to this action must be filed with the Clerk of this Court within a reasonable period of time after service.

*J. E. NOBLIN*

CLERK

*51*

(By) DEPUTY CLERK

DATE

*11-20-07*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI**

**ESTATE of BOBBIE G. OVERTON, SR., by  
Personal Representative of the Estate, BOBBIE  
H. OVERTON, ESTATE of JAMES ELLIS,  
CAROLYN EVANS, RUBY GILES, RICHARD  
GRIFFITH, ELAINE JOYCE LEE, ESTATE  
OF CORNELIA LEWIS, JACKIE LEWIS,**

**PLAINTIFFS**

**vs.**

**CIVIL ACTION NO. 3:07-cv-450-TSL-JCS**

**Pending Transfer to MDL-1699  
(In re Bextra and Celebrex Marketing,  
Sales Practices and Products  
Liability Litigation)**

**PFIZER INC., MONSANTO COMPANY, G.D.  
SEARLE LLC, and PHARMACIA  
CORPORATION,**

**DEFENDANTS**

**DEFENDANTS' ANSWER AND DEFENSES TO PLAINTIFFS' COMPLAINT**

NOW COME Defendants Pfizer Inc. ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company<sup>1</sup>) ("Pharmacia"), and G.D. Searle LLC ("Searle") (collectively "Defendants"), and file their Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

---

<sup>1</sup> Plaintiffs' Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. Given that Plaintiffs allege in the Complaint that Monsanto Company was involved in distributing Celebrex®, *see* PLAINTIFFS' COMPLAINT at ¶ 7, Defendants assume Plaintiffs mean to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.



**I.****PRELIMINARY STATEMENT**

The Complaint does not state in sufficient detail when Plaintiffs and Decedents were prescribed or used Celebrex® (celocoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs and Decedents was prescribed and used Celebrex®.

**II.****ORIGINAL ANSWER****Response to Introduction**

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Allegations Regarding Jurisdiction and Venue**

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of interests and costs.
3. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required.
4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which

the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the State of Mississippi and deny the remaining allegations in this paragraph of the Complaint.

**Response to Allegations Regarding Parties**

- a. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's or Decedent's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.
- b. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.
- c. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.
- d. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.
- e. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.
- f. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's or Decedent's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this

paragraph of the Complaint.

g. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

h. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's or Decedent's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that Searle may be served through its registered agent. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey and that Pharmacia is registered to do business in the State of Mississippi. Defendants admit that Pharmacia may be served through its registered agent. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was

incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

8. Defendants admit that Pfizer is a Delaware corporation and that Pfizer is registered to do business in Illinois. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

#### **Response to Allegations Regarding Joinder**

9. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' and Decedents' medical conditions and whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

10. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' and Decedents' medical conditions and whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-

approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

#### **Response to Background Allegations**

12. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any

wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' and Decedents' medical conditions and whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® caused Plaintiffs or Decedents injury or damage and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.



17. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

19. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiffs claim that the amount in controversy meets jurisdictional limits. Defendants deny the remaining allegations in this paragraph of the Complaint.

20. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being a non-steroidal anti-inflammatory (“NSAID”) drugs. Defendants deny the remaining allegations in this paragraph of the Complaint.

21. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is

deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

22. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

23. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.

24. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the remaining allegations in this paragraph. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of the allegations, and, therefore, deny the remaining allegations in this paragraph of the Complaint.

25. Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he



mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

26. Defendants admit that Searle submitted a New Drug Application (“NDA”) for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

29. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

30. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

32. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20, 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself

and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Plaintiffs fail to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is

denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public Citizen” in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

47. Defendants admit that there was a clinical trial called APC. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide the proper context for the allegations concerning “other Celebrex trials” contained in this

paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. As for the allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced studies speaks for themselves and respectfully refer the Court to the studies for their actual language and text. Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

56. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text.



Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

60. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is

denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

61. Defendants state that allegations in this paragraph of the Complaint are not directed toward Defendants, and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Defendants deny the allegations in this paragraph of the Complaint.

63. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

64. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

65. Defendants deny any wrongful conduct and deny the allegations contained in this paragraph of the Complaint.

66. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

67. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing



information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

71. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-

promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

75. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants deny the allegations in this paragraph of the Complaint.

80. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

85. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

the Complaint.

86. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

**Response to First Cause of Action: Negligence**

88. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but denies having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.



91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

92. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

93. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

96. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Second Cause of Action: Strict Products Liability Defective Design**

97. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

98. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately



described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

102. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

105. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Third Cause of Action: Strict Products Liability Failure to Warn**

106. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

107. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

109. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

110. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

111. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

112. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but denies having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any

wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Fourth Cause of Action: Breach of Express Warranty of Merchantability**

117. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

118. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

119. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

120. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

122. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Fifth Cause of Action: Breach of Implied Warranty of Merchantability**

124. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

125. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

126. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

127. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants Pfizer, Pharmacia, and Searle admit that they provided FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

128. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately



described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

129. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

130. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny any breach of warranty, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

131. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

132. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations

in this paragraph of the Complaint.

134. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

135. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Sixth Cause of Action: Fraud**

136. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

137. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

138. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

139. Defendants state that Celebrex® was and is safe and effective when used in accordance



with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

140. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

142. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

143. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

144. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but denies having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

145. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

146. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or

Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

147. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

148. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

149. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Seventh Cause of Action: Negligent Misrepresentation**

151. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

152. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

153. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and

Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

154. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

155. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

157. Defendants are without knowledge or information sufficient to form a belief as to the

truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

158. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

159. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but denies having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

160. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was

and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

161. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

162. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

163. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

164. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 170 of the Complaint, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedents injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

### III.

#### **GENERAL DENIAL**

Defendants deny the allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

**AFFIRMATIVE DEFENSES**

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

**First Defense**

1. The Complaint fails to state a claim upon which relief can be granted.

**Second Defense**

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

**Third Defense**

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

**Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.



**Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs and Decedents was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiffs should be diminished accordingly.

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs or Decedents were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or Decedents.

**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' and Decedents' treating and prescribing physicians.



**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs and Decedents was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiffs' and Decedents' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiffs' and Decedents' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

**Nineteenth Defense**

19. Plaintiffs and Decedents knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twentieth Defense**

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the

Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical

product at issue “provides net benefits for a class of patients” within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiffs’ claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. The imposition of punitive damages in this case would violate Defendants’ rights to procedural due process under the Fourteenth Amendment of the United States Constitution and Constitution of the State of Mississippi, and would additionally violate Defendants’ right to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiffs’ claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution and the Constitution of the State of Mississippi.

**Thirty-third Defense**

33. Plaintiffs’ punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants’ nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiffs and Decedents failed to provide Defendants with timely notice of any alleged

nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of the State of Mississippi. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs and Decedents; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and Decedents and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6)

lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

#### **Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

#### **Fortieth Defense**

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

#### **Forty-first Defense**

41. If Plaintiffs and Decedents have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

#### **Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**Forty-third Defense**

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

**Forty-fourth Defense**

44. Plaintiffs' claims are barred because Plaintiffs' and Decedents' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs and Decedents, and were independent of or far removed from Defendants' conduct.

**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs or Decedents.

**Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedents did not incur any ascertainable loss as a result of Defendants' conduct.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiffs and Decedents would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

**Fiftieth Defense**

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedents.

**Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**Fifty-fourth Defense**

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.



**Fifty-fifth Defense**

55. To the extent that Plaintiffs rely upon any theory of breach of warranty, his or her claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiffs failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

**Fifty-sixth Defense**

56. Any verdict or judgment rendered against Defendants must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs and/or Decedents, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs and/or Decedents may have settled his or her claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs and/or Decedents and any such parties.

**Fifty-seventh Defense**

57. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

**Fifty-eighth Defense**

58. Defendants assert that Plaintiffs' claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

**Fifty-ninth Defense**

59. Celebrex® and the Defendants' actions conformed to the state of the art medical and scientific knowledge at all times relevant to this lawsuit and/or Celebrex® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts:



Products Liability § 4.

**Sixtieth Defense**

60. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiffs' claims are therefore barred.

**Sixty-first Defense**

61. Plaintiffs' allegations of fraud, deceit, and fraudulent misrepresentation are not stated with the degree of particularity required by F.R.C.P. 9(b) and should be dismissed.

**Sixty-second Defense**

62. Answering Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

**Sixty-third Defense**

63. Plaintiffs failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Answering Defendants in any possible future litigation.

**Sixty-fourth Defense**

64. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to ward, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

**Sixty-fifth Defense**

65. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical products at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Sixty-sixth Defense**

66. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any

award of punitive damages is barred.

**Sixty-seventh Defense**

67. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

**Sixty-eighth Defense**

68. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

**V.**

**JURY DEMAND**

Defendants hereby demand a trial by jury.

**VI.**

**PRAYER**

WHEREFORE, Defendants pray that Plaintiffs take nothing by this suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which it may be justly entitled.

This the 17<sup>th</sup> day of December, 2007.

Respectfully submitted,

By: /s/ Walter T. Johnson

Walter T. Johnson (MBN 8712)  
Joseph J. Stroble (MBN 10779)  
WATKINS & EAGER, P.L.L.C.  
400 East Capitol Street, Suite 300  
Jackson, Mississippi 39205-0650  
Telephone: (601) 948-6470  
Facsimile (601) 354-3623

OF COUNSEL:

SOCHA, PERCZAK, SETTER & ANDERSON, P.C.  
Charles Q. Socha (MBN 101382)  
K. Michelle Anderson (MBN 101421)  
Denver Financial Center Tower 1  
1775 Sherman Street, Suite 1925  
Denver, Colorado 80203  
Telephone: (303) 832-7265  
Facsimile: (303) 832-7438

ATTORNEYS FOR PFIZER INC., PHARMACIA  
CORPORATION, and G.D. SEARLE LLC

**CERTIFICATE OF SERVICE**

I hereby certify that on December 17, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF system and forwarded on December 17, 2007, via United States first-class mail, postage prepaid, a true and correct copy to the following:

Levi Boone, III  
BOONE LAW FIRM, P.A.  
401 West Sunflower Road  
P.O. Box 1722  
Cleveland, Mississippi 38732-1772

/s/ Walter T. Johnson  
Walter T. Johnson

UNITED STATES DISTRICT COURT  
OFFICE OF THE CLERK  
SOUTHERN DISTRICT OF MISSISSIPPI  
Jackson, Mississippi

January 11, 2008

J. T. Noblin  
CLERK

245 E. Capitol St., Suite 316  
Jackson, MS 39201

TELEPHONE  
(601) 965-4439

*DIVISIONS*

SOUTHERN at Gulfport  
2012 15<sup>th</sup> Street, Suite 403  
Zip 39501

HATTIESBURG at Hattiesburg  
701 Main St., Room 200, Zip 39401

JACKSON at Jackson  
245 E. Capitol, Suite 316  
Zip 39201

EASTERN & WESTERN at Jackson  
245 E. Capitol, Suite 316  
Zip 39201

Mr. Michael J. Beck, Clerk  
Judicial Panel on Multidistrict Litigation  
1 Columbus Circle, NE #G-255  
Washington, D. C. 20002-8000

Re: MDL - **Celexa and Lexapro Products Liability Litigation, MDL No. 1736\*\***  
Civil Action No. 3:07cv450


Dear Mr. Beck:

It has come to the attention of the clerk's office that the captioned litigation may involve issues related to **Celexa and Lexapro Products Liability Litigation, MDL No. 1736\*\***. If so, this litigation may be subject to the jurisdiction of the Multidistrict Litigation Panel, MDL Panel.

According to the directive of your office, we enclose a copy of the docket sheet, as well as a copy of the complaint which has been filed in this cause. By copy of this letter, we are noticing the attorneys for the parties of this action.

If we can provide any additional or more specific information concerning the status of this case, we will be pleased to promptly do so.

Yours very truly,

  
J. T. Noblin, Clerk

JTN:jkm

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI  
JACKSON DIVISION

BOBBIE H. OVERTON

PLAINTIFF

VERSUS

CIVIL ACTION NO. 3:07cv450-TSL-JCS

PFISER, INC., ET AL.

DEFENDANT

---

ORDER

THIS CAUSE comes before the Court *sua sponte* to stay discovery pending transfer to MDL. A review of the docket entries herein indicates that all discovery should be stayed pending the potential transfer of this case to Multi-District Litigation.

IT IS, THEREFORE, ORDERED that all discovery should be stayed in this case pending the potential transfer of this case to Multi-District Litigation, and the parties shall inform the court of that decision within five days of receipt of same.

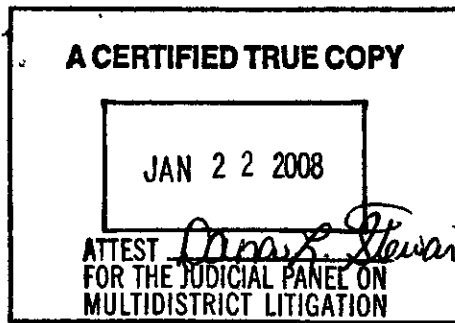
IT IS FURTHER ORDERED that the Telephonic Case Management Conference scheduled in this case is hereby cancelled.

SO ORDERED, this the 11<sup>th</sup> day of January, 2007.

/s/ James C. Sumner

---

UNITED STATES MAGISTRATE JUDGE

JUDICIAL PANEL ON  
MULTIDISTRICT LITIGATION

JAN - 3 2008

FILED  
CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL  
on  
MULTIDISTRICT LITIGATION

IN RE: BEXTRA AND CELEBREX MARKETING, SALES  
PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 1699

(SEE ATTACHED SCHEDULE)

**CONDITIONAL TRANSFER ORDER (CTO-92)**

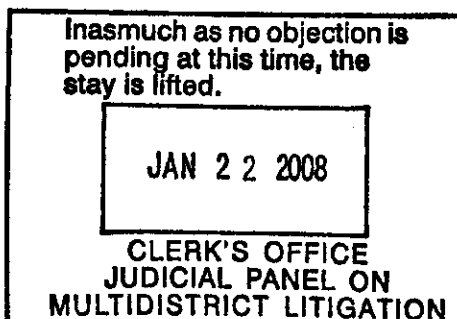
On September 6, 2005, the Panel transferred 30 civil actions to the United States District Court for the Northern District of California for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. *See* 391 F.Supp.2d 1377 (J.P.M.L. 2005). Since that time, 1,167 additional actions have been transferred to the Northern District of California. With the consent of that court, all such actions have been assigned to the Honorable Charles R. Breyer.

It appears that the actions on this conditional transfer order involve questions of fact that are common to the actions previously transferred to the Northern District of California and assigned to Judge Breyer.

Pursuant to Rule 7.4 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, 199 F.R.D. 425, 435-36 (2001), these actions are transferred under 28 U.S.C. § 1407 to the Northern District of California for the reasons stated in the order of September 6, 2005, and, with the consent of that court, assigned to the Honorable Charles R. Breyer.

This order does not become effective until it is filed in the Office of the Clerk of the United States District Court for the Northern District of California. The transmittal of this order to said Clerk shall be stayed 15 days from the entry thereof. If any party files a notice of opposition with the Clerk of the Panel within this 15-day period, the stay will be continued until further order of the Panel.

FOR THE PANEL:



*Jeffery N. Luthi*  
Jeffery N. Luthi  
Clerk of the Panel

I hereby certify that the annexed  
instrument is a true and correct copy  
of the original on file in my office.  
ATTEST:

RICHARD W. WIEKING  
Clerk, U.S. District Court  
Northern District of California  
By *Sharon Volk*

Date 1-23-08



IN RE: BEXTRA AND CELEBREX MARKETING, SALES  
PRACTICES AND PRODUCTS LIABILITY LITIGATION

MDL No. 1699

SCHEDULE CTO-92 - TAG-ALONG ACTIONS

DIST. DIV. C.A. #

CASE CAPTION

ALABAMA NORTHERN

ALN 3 07-2219

Raymond Beaver v. Pfizer Inc., et al.

MARYLAND

MD 1 07-3205

Ronald N. Price, Sr., etc. v. Pfizer Inc.

MD 1 07-3206

Martin Fisher, etc. v. Pfizer Inc.

MINNESOTA

MN 0 07-4791

Robert Colman v. Pfizer Inc., et al.

MN 0 07-4801

Harriet Bratcher v. Pfizer Inc., et al.

MISSISSIPPI SOUTHERN

MSS 3 07-450

Bobbie H. Overton, et al. v. Pfizer Inc., et al.

CJRA-SU, CLOSED, JCS, JURY

**U.S. District Court  
Southern District of Mississippi (Jackson)  
CIVIL DOCKET FOR CASE #: 3:07-cv-00450-TSL-JCS**

Overton v. Pfizer Inc. et al  
Assigned to: District Judge Tom S. Lee  
Referred to: Magistrate Judge James C. Sumner  
Cause: 28:1332 Diversity-Personal Injury

Date Filed: 08/02/2007  
Date Terminated: 02/04/2008  
Jury Demand: None  
Nature of Suit: 365 Personal Inj.  
Prod. Liability  
Jurisdiction: Diversity

**Plaintiff**

**Bobbie H. Overton**  
*Estate of Bobbie G. Overton, Sr.,  
James Ellis, Carolyn Evans, Ruby  
Giles, Richard Griffin, Elaine  
Joyce Lee, Cornelius Lewis and  
Jackie Lewis*

represented by **Levi Boone, III**  
BOONE LAW FIRM, PA  
P. O. Box 1772  
Cleveland, MS 38774  
662/843-7946  
Fax: 662/843-7950  
Email:  
lboone@boonelawfirm.com  
*LEAD ATTORNEY*  
*ATTORNEY TO BE NOTICED*

V.

**Defendant**

**Pfizer Inc.**

represented by **Walter T. Johnson**  
WATKINS & EAGER  
P. O. Box 650  
Jackson, MS 39205-0650  
(601) 948-6470  
Email:  
wjohnson@watkinseager.com  
*ATTORNEY TO BE NOTICED*

**Defendant**

**Monsanto Company**

represented by **Walter T. Johnson**  
(See above for address)

*ATTORNEY TO BE NOTICED***Defendant****G. D. Searle LLC**represented by **Walter T. Johnson**  
(See above for address)  
*ATTORNEY TO BE NOTICED***Defendant****Pharmacia Corporation**represented by **Walter T. Johnson**  
(See above for address)  
*ATTORNEY TO BE NOTICED*

<b>Date Filed</b>	<b>#</b>	<b>Docket Text</b>
02/04/2008	<a href="#"><u>9</u></a>	CERTIFIED COPY OF CONDITIONAL TRANSFER ORDER re Remark, (JKM) (Entered: 02/04/2008)
02/04/2008	<a href="#"><u>9</u></a>	Remark - Case transferred to USDC, Northern District of California, 450 Golden Gates Avenue, Post Office Box 36060, San Fransico, CA 94102. Attn: Simone Voltz. MDL letter regarding instructions for electronic record, attached all pdf documents and docket sheet via email to Simone Voltz per letter received on 2/4/08. (JKM) (Entered: 02/04/2008)
01/11/2008	<a href="#"><u>8</u></a>	ORDER STAYING DISCOVERY pending transfer to MDL as set out. The telephonic case management conference scheduled in this case is hereby cancelled. Signed by Judge James C. Sumner on January 11, 2008 (CSF) (Entered: 01/11/2008)
01/11/2008	<a href="#"><u>7</u></a>	Letter sent to MDL Clerk with docket entries and complaint/notice of removal. (JKM) (Entered: 01/11/2008)
12/28/2007	<a href="#"><u>6</u></a>	Rule 16.1(A) Initial Order Telephonic Case Management Conference set for 2/12/2008 09:30 AM before Magistrate Judge James C. Sumner (CSF) (Entered: 12/28/2007)
12/17/2007	<a href="#"><u>5</u></a>	Corporate Disclosure Statement by Pfizer Inc., Monsanto Company, G. D. Searle LLC, Pharmacia Corporation (Johnson, Walter) (Entered: 12/17/2007)
12/17/2007	<a href="#"><u>4</u></a>	<i>Defendants' Answer and Defenses to Plaintiffs' Complaint</i> ANSWER to Complaint by Pfizer Inc., Monsanto Company, G. D. Searle LLC, Pharmacia Corporation.(Johnson, Walter) (Entered: 12/17/2007)

11/20/2007	● <u>3</u>	Summons Issued as to Pfizer Inc., Monsanto Company, G. D. Searle LLC, Pharmacia Corporation. (JKM) (Entered: 11/20/2007)
09/18/2007	● <u>2</u>	ORDER OF RECUSAL. Judge Henry T. Wingate recused. Case reassigned to Judge Tom S. Lee for all further proceedings Signed by Judge Henry T. Wingate on 9/18/07 (JKM) (Entered: 09/19/2007)
08/07/2007	● <u>1</u>	COMPLAINT against Pfizer Inc., Monsanto Company, G. D. Searle LLC, Pharmacia Corporation ( Filing fee \$ 350 receipt number J020542), filed by Bobbie H. Overton. Jury Demand (Attachments: # <u>1</u> Civil Cover Sheet)(JKM) Modified on 8/7/2007 (JKM). Additional attachment(s) added on 11/20/2007 (JKM). (Entered: 08/07/2007)